REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on July 18, 2007, and the references cited therewith.

Claims 1, 8, 10-11, 13-16, 19, and 27-28 are amended, claims 4-7, 12, 18, 24, are canceled, and claims 40-41 are added; as a result, claims 1-3, 8-11, 13-17, 19-23, 25-41 are now pending in this application.

Claim Objections

Regarding item 2 of the Office Action dated July 18, 2007, the Examiner objected to claims 5, 6, 7, 10-12, 18 and 19. Claims 5-7, 12, and 18 are canceled. As to claims 10-11 and 19, the Examiner's suggested claim language has been adopted.

§112 Rejection of the Claims

Regarding item 3 of the Office action dated July 18, 2007, claims 1-28 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-3, 8-11, 13-17, 21-28 and 40-41 have been amended to include species of a multifunctional crosslinking agent and species of a cross-linkable biomolecule. Support for the claim language is found in the specification as filed (see claims 5 and 23 and for example, Examples 1-6). Further independent claims 1 and 8 have been amended to incorporate the terms "adsorbable biomolecule" (defined on page 16, lines 9-15) and silyl-group (defined on page 17, lines 17-24).

Regarding item 4 of the Office Action dated July 18, 2007, claims 19-22 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 19-22 are amended as suggested by the Examiner thereby rendering this claim moot.

§102 Rejection of the Claims

Regarding item 5 of the Office Action dated 7/18/2007, claims 1-2, 4-12, 16 and 18 were rejected under 35 USC §102(e) as being anticipated by Hossainy et al. (U.S.6585765). Applicant traverses the rejection.

The Examiner states that "Hossainy teaches a method of impregnating an implantable device such as a vascular graft or a covering adapted to be disposed over a prosthesis comprising applying said device with a solution comprising a pre-polymer crosslinking agent (e.g., polyethylene glycol, polyvinylpyrrolidone, dimethylaminoethyl methacylate, etc.)." The Examiner goes on to state that subsequently, applying the device with a solution comprising a cross-linkable therapeutic agent wherein said crosslinking agent is crosslinked with said therapeutic agent, forming hydrogel and impregnated to said device.

Hossainy fails to teach each and every limitation of independent claims 1 and 8 as Hossainy fails to teach a coating or an absorbed coating. Hossainy teaches "A method of impregnating an implantable device (implantable body) with a hydrogel... said body having cavities disposed therein," such that the pre-polymer crosslinks to form a hydrogel within the cavities of the implantable body. Hossainy states throughout that the hydrogel "will remain in the interstices of the graft" (see samples 1-7). The hydrogel formed by Hossainy is a colloidal gel physically trapped within and restricted to the cavities of the device. It is therefore not a coating; Hossainy does not teach a method of coating a surface such as the top or bottom of a device. Nor is there way to clearly infer that Hossainy will coat or be adsorbed onto any surface whatsoever.

Amended independent claims 1 and 8 teach "A method of forming a cross-linked coating on a medical device... with cross-linkable biomolecule rendered surface adsorbable by conjugation with 1-30 hydrophobic benzylated silyl groups."

Supposing that heparin is the therapeutic as described by Hossainy, heparin would form a bond only with the crosslinking agent. It would not be crosslinked to the medical device, or adsorbed onto the medical device with or without crosslinking as heparin is hydrophilic (as is the hydrogel) whereas the graft materials of Hossainy ePTFE, PET, and PU are highly hydrophobic. Therefore, the heparin of Hossainy is not an adsorbable biomolecule as is required by amended independent claims 1 and 8.

Amended independent claims 1 and 8 call for the use of a cross-linkable biomolecule rendered surface adsorbable by conjugation with 1-30 hydrophobic benzylated silyl groups. Again, nowhere in Hossainy is there implicit or implied mention of surface adsorbable biomolecules to produce a coating.

In light of the aforementioned, Hossainy fails to teach each element of independent claims 1 and 8. Therefore independent claims 1 and 8 as amended are patentable over Hossainy. Claim 2 depends from claim 1 and claims 9-11 and 16 depend from claim 8 and are patentable for at least the reasons stated in support of claims 1 and 8.

§103 Rejection of the Claims

Regarding item 6 of the Office Action dated 7/18/2007, claims 3, 14-15, 17 and 25-28 were rejected under 35 USC §103(a) as being unpatentable over Hossainy (U.S.6545765). The Examiner states that Hossainy teaches the invention as claimed. Applicant traverses the rejection. Claim 3 depends from claim 1. Claims 14-15, 17, and 25-28 depend from claim 8.

Hossainy teaches away from independent claims 1 and 8 as amended in that Hossainy teaches the construction of a hyrogel (gel) physically trapped within a cavity (interstice, pore), and does not teach a coating or an absorbed coating. Hossainy teaches "A method of impregnating an implantable device (implantable body) with a hydrogel... said body having cavities disposed therein," such that the pre-polymer crosslinks to form a hydrogel within the cavities of the implantable body. Hossainy states throughout that the hydrogel "will remain in the interstices of the graft" (see samples 1-7). The hydrogel formed by Hossainy is colloidal gel physically trapped within and restricted to the cavities of the device. It is therefore not a coating. Hossainy does not teach a method of coating a surface such as the top or bottom of a device. Nor is there way to clearly infer that Hossainy will coat or be adsorbed onto any surface whatsoever.

Amended independent claims 1 and 8 teach "A method of forming a cross-linked coating on a medical device..." with cross-linkable biomolecule rendered surface adsorbable by conjugation with 1-30 hydrophobic benzylated silyl groups". Amended independent claims 1 and 8 claim as an element the surface coating limitation which is not found or taught by Hossainy.

Hossainy first adds crosslinking agent to the device to impregnate the pores of the device. The device having crosslinker solution filling its pores is then exposed to a therapeutic agent which reacts with the crosslinking agent to form a covalent bond. The crosslinker subsequently forms a crosslinked hydrogel that is immobilized in the pores. Supposing that heparin is the therapeutic as described by Hossainy, heparin would form a bond only with the crosslinking agent. It would not be crosslinked to the medical device, or adsorbed onto the medical device with or without crosslinking as heparin in hydrophilic (as is the hydrogel) whereas the graft materials of Hossainy ePTFE, PET, and PU are highly hydrophobic. Therefore, the heparin of Hossainy is not an adsorbable biomolecule as is required by amended independent claims 1 and 8.

Amended independent claims 1 and 8 call for the use of a cross-linkable biomolecule rendered surface adsorbable by conjugation with 1-30 hydrophobic benzylated silyl groups. Again, nowhere in Hossainy is there implicit or implied mention of surface adsorbable biomolecules to produce a coating.

Also, the application as originally filed states that a method similar to Hossainy was inferior to the present invention because "In the case of heparin activity biomolecules, cross-linking with a multifunctional crosslinking agent such as BTC-PEG did not result in the desired residence time of the coating where the heparin did not contain one or more hydrophobic prosthetic units, such as a silyl moiety. Thus cross-linked silyl-heparin had a statistically relevant longer residence time than did cross-linked heparin.", thereby demonstrating the improvement gained by use of silyl-heparin and the method of amended independent claim 1 and 8.

In contrast to Hossainy, amended claim 1 states the biomolecule is rendered adsorbable by chemical conjugation to hydrophobic benzylated silyl groups. The silyl-biomolecule is adsorbed onto all surfaces of the device and crosslinked within the plane of surface (and within the pores).

Also in contrast to Hossainy, the original application stated "It has surprisingly been found that the residence time of the covalently cross-linked co-polymer coating, such as in vivo residence time after coating on a vascular graft composed of ePTFE, is longest when the multifunctional crosslinking agent is applied first, followed by application of the adsorbable

biomolecule in an organic solvent including water, and then followed by a second application of the multifunctional crosslinking agent." Such a tripartite construction is not described by Hossainy.

In light of the aforementioned, Hossainy teaches away from independent claims 1 and 8 as amended. Therefore independent claims 1 and 8 as amended are patentable over Hossainy. Claim 3 depends from claim 1 and claims 14-15, 17, and 25-28 depend from claim 8 and are patentable for at least the reasons stated in support of claims 1 and 8.

Claims 14-15, 17 and 25-28 depend from claim 8. Amended claim 8 recites the element that the device is immersed in the first solution containing the crosslinking agent after the device has been immersed in the second solution. Hossainy fails to teach this method as Hossainy teaches the device is immersed in the crosslinking solution first to coat the device and only then is the device exposed to the solution containing the therapeutic agent.

Regarding item 7, claims 13 and 19-24 were rejected under 35 USC ' 103(a) as being unpatentable over Hossainy (U.S.6545765) in view of Sawney (U.S. 6818018) in view of Tsang et al. (U.S. 5955588).

As discussed above, Hossainy teaches immersing the device in a solution containing a crosslinking agent to impregnate the cavities of a device. The device is immersed in a solution containing a therapeutic agent which bonds to the crosslinker and forms a hydrogel that is contained within the cavities of the device. The heparin is not adsorbable to the device. In contrast, claim 8 teaches a coating which coats the device with an adsorbable biomolecule that is cross-linkable and the biomolecule is adsorbed onto the device, and biomolecule binds to a crosslinker to form a coating. Hossainy teaches a hydrogel formed in pores. Hossainy does not teach a solution containing a cross-linkable biomolecule rendered surface adsorbable by conjugation with 1-30 hydrophobic benzylated silyl-groups.

The references of Sawney or Tsang fail to remedy the deficiency of Hossainy. Therefore the *prima facie* case of obviousness fails and claims 21-22 should be found patentable over the combination of references.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (505-998-6134) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-4213

Respectfully submitted,

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